K 102476

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VIDAR
systems corporation
The Image of Reliability

510(k) Summary

Submitter: VIDAR Systems Corporation
365 Herndon Parkway
Herndon, VA 20170 U.S.A.
703-471-7070 (phone)
703-471-1165 (fax)

OCT 7 2010

Official Correspondent: Carrie L. Brancart

Date of Submittal: August 23, 2010

Trade Name: TeleradPRO

Common Name: X-Ray Film Digitizer

Classification Name: Medical Image Digitizer (21 CFR 892.2030)
Product Code: LMA
Predicate Device: Trade Name: TeleRADPro Film Digitizers
510(k): K993597

Manufacturer: VIDAR Systems Corporation

Device Description:
The device consists of a film digitizer with single-film or multi-film feeder, external power adapter, and Windows driver software. The film digitizer will convert the X-ray film into digital data representing the X-ray film, and the windows driver software is used to import the digital data into a compatible software application

The Digitizer is connected to a PC through a USB 2.0 interface. The digitizer utilizes rollers driven by a stepper motor to feed the X-ray film past the scan optics. The scan optics consists of a white LED illuminator, a lens, mirrors, and a CCD linear array detector.

Intended Use:
The VIDAR TeleradPRO film digitizer is used for making digital copies of medical x-ray films.

The intended use of the modified device, as described in its labeling, has not changed as a result of the modifications.

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Technological Characteristics:
The VIDAR TeleradPRO film digitizer offers a high optical resolution of 300 dpi; 16-bit grayscale, optical density sensitivity (DMAX) of 4.8 OD, and a medical OD range of 0.2 – 3.2 (incorporates noise and linearity measurements).

Performance Testing:
VIDAR conducts extensive performance testing and the test results demonstrate the device meets the requirements for its intended use. Please see Section 22 Bench Testing.

Substantial Equivalence to Predicate Device:
The TeleradPRO is substantially equivalent to TeleRADPro film digitizer. The comparison table of the principal characteristics of the two devices is shown in Section 14 and specification data for the TeleradPRO is included in Section 13.

Conclusion:
In terms of intended use, function, safety, operating environmental conditions and effectiveness of the TeleradPRO it is determined to be substantially equivalent to the predicate device used for this application.

365 Herndon Parkway
Herndon, VA 20170 • USA 800.471.SCAN +1.703.471.7070 Fax: +1.703.471.1165

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Carrie L. Brancart
Director, Quality Assurance and Regulatory Affairs
Vidar Systems Corporation
365 Herndon Parkway
HERNDON VA 20170

OCT 7 2010

Re: K102476
Trade/Device Name: TeleradPRO
Regulation Number: 21 CFR 892.2020
Regulation Name: Medical image communications device
Regulatory Class: II
Product Code: LMA
Dated: August 23, 2010
Received: August 30, 2010

Dear Ms. Brancart:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

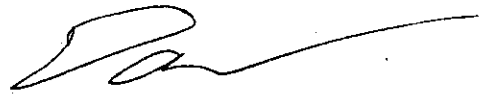
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

VIDAR Systems Corporation K 102476

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: TeleradPRO

Indications for Use:

The TeleradPRO film digitizer is intended for making digital copies of medical x-ray films.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ OIVD

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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